K090431
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SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

JUN 22 2009

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person

Date Summary Prepared: February 4, 2009

Device Name:

- Trade Name – ***DEXIS Software***
- Common Name – Dental Imaging Device
- Classification Name – Picture Archiving and Communication Systems, per 21 CFR § 892.2050.

Devices for Which Substantial Equivalence is Claimed:

- Fair Image, Inc., (now owned by DEXIS, LLC.), *DEXIS Model 601 (K962631)*
- Gendex Dental Systems, *VixWin Pro (K060178)*

Device Description:

The DEXIS Software is a software program for general dental and maxillo-facial diagnostic imaging. It controls capture, display, enhancement and saving of x-ray digital images from digital imaging systems. It can also handle other types of images acquired by digitizing film with a flat bed scanner, or color images from intraoral or extraoral dental cameras. DEXIS Software allows the following functionality:

- Control scanning and intake of x-ray images from imaging plates with the DenOptix scanner.
- Control the direct capture of x-ray images from the intraoral sensor Visualix / GX-S, KaVo Dig eXam, Orthoralix DPI & DDE series systems.
- View and capture color images from certain cameras, such as dental camera, via a suitable video capture card.
- Export and import digital images (such as those obtained by scanning a film) in several standard file formats.
- Process images with dental specific tools, to enhance their diagnostic value.
- Analyze and manipulate images in order to gather additional diagnostic information which may not be immediately apparent on initial visual inspection.
- Create a database of patients and easily store images in patient folders.

Intended Use of the Device:

The DEXIS software is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement and saving of X-ray digital images from digital imaging systems. It can also handle other types of images acquired by digitizing film with a flat bed scanner, or color images from intra-oral and extra-oral dental cameras.

Substantial Equivalence:

The *DEXIS Software* is an existing device which was granted market clearance by the FDA following the submission of a 510(k) pre-market notification (K962631). The modified DEXIS Software has been rewritten in 32-bit code and will now run in 'native' format with Microsoft® Windows XP® (home or professional) and Windows® 2000. The modified device also retains 'backward compatibility' with earlier versions including Windows® 98, NT and non-upgrade versions of ME. There will be no change to the intended use or technical characteristics.

The *DEXIS Software* is substantially equivalent in intended use and technical characteristics as the VixWin Pro software marketed by Gendex Dental Systems (K060178).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2009

DEXIS LLC
%Ms. Claudia Ortiz
Compliance Director, Regulatory Affairs & Quality Assurance
Sybron Dental Specialties
1717 West Collins Avenue
ORANGE CA 92867

Re: K090431
Trade/Device Name: DEXIS Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 27, 2009
Received: June 2, 2009

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090431

Device Name: DEXIS Software

Indications for Use:

The DEXIS software is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement and saving of X-ray digital images from digital imaging systems. It can also handle other types of images acquired by digitizing film with a flat bed scanner, or color images from intra-oral and extra-oral dental cameras.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
of Reproductive, Abdominal,
ological Devices
Number K090431